UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BRUNO HOFMANN

v.

PHILIP LAUGHLIN, et al.

Civ. No. 04-10027-JLT

ORAL ARGUMENT REQUESTED

MEMORANDUM OF DEFENDANTS ALBERT ERANI, PHILIP LAUGHLIN, DONNA ABELLI LOPOLITO, MICHAEL SABOLINSKI, ALAN TUCK AND HERBERT STEIN IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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Dated: April 18, 2007

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Pursuant to Federal Rule of Civil Procedure 56, defendants Albert Erani, Philip Laughlin, Donna Abelli Lopolito, Michael Sabolinski, Alan Tuck and Herbert Stein (hereinafter, "defendants") move for summary judgment on the only claims remaining in this case, which are the *individual* claims asserted by *one* plaintiff (Bruno Hofmann) against some defendants under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder (Count I) and a "control person" claim under Section 20(a) of the Exchange Act (Count II).

INTRODUCTION

There is very left to litigate in this case. It is *not* a class action because the Court denied the Motion for Class Certification filed by former Lead Plaintiffs Hofmann and Richard Madigan. The Court also has held that Madigan cannot even assert any individual claims because he has no damages (having actually profited from the allegedly inflated stock price) and found that Hofmann has no standing to pursue any claims against former defendant John Arcari. All claims against former defendants Alan Ades and PricewaterhouseCoopers ("PwC") were dismissed previously. And former named plaintiffs Richard Conen and John Bowie, Jr. withdrew from the case. The *only* claims remaining in this case are the individual (not class) claims of Hofmann against defendants Erani, Laughlin, Lopolito, Sabolinski, Tuck and Stein, and they are now very narrow.

Summary judgment should be granted on Hofmann's remaining individual claims. As the Court made clear at the hearing on February 5, 2007, Hofmann cannot rely on the allegations in the Complaint to oppose summary judgment as he could at the motion to dismiss stage.[1] He also has no evidence to support his claims. First, Hofmann does not have standing to base a

[1] "That is not a victory, denial of a motion to dismiss. I have to look at what is alleged and take it to be true . . . . As long as somebody can articulate some language that passes minimum muster, then you survive the motion to dismiss. A motion for summary judgment is a different ball game." Transcript of Motion Hearing dated February 5, 2007, Dkt. No. 200 at 45.

lawsuit on any of the alleged misrepresentations made *after* Hofmann's last purchase of stock in Organogenesis, Inc. ("Organogenesis") in April 2000 (Challenged Statements Nos. 10-39) because he could not possibly have relied on or been misled by them, which disposes of most of the lawsuit previously brought as a putative class action. Second, Hofmann's individual claims based on remaining Challenged Statements Nos. 1-9 cannot survive summary judgment because, as a matter of law, those statements are either immaterial, or indisputably true, or both.[2] Third, in the alternative, even if Hofmann had evidence of a material misrepresentation, there is no evidence of loss causation.

Nor is this a case where summary judgment could be postponed because of any supposed need to take more discovery. Hofmann certainly cannot invoke Federal Rule of Civil Procedure 56(f) because he had an entire *year* to take discovery under the Court's Scheduling Order, dated April 26, 2006, and did virtually nothing during that time. But more fundamentally, no amount of additional discovery would help him because this motion is based entirely on *publicly-available, judicially-noticeable documents*. The public documents unequivocally show that Challenged Statements Nos. 1-9 were not false or misleading and that there is no loss causation. Summary judgment should be granted on all remaining claims in this case.

ARGUMENT

I. THE ONLY REMAINING CLAIMS ARE THE INDIVIDUAL CLAIMS OF BRUNO HOFMANN.

The only claims remaining in this case are Hofmann's individual claims against defendants Erani, Laughlin, Lopolito, Sabolinski, Tuck and Stein:

- The Court denied the Motion for Class Certification filed by former Lead Plaintiffs Hofmann and Madigan. See Memorandum dated March 15, 2007 (Dkt.

[2] A Chart of Challenged Statements containing each statement challenged as misleading in the Complaint has been filed herewith as an Appendix.

No. 209). Accordingly, any claims on behalf of absent class members are not at issue in this action.

- The Court held that Madigan has no damages, see id. at 7-12, and thus he cannot maintain any claims against anyone. See Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005) ("economic loss" is an essential element of Section 10(b) claim); In re Stone & Webster, Inc. Sec. Litig., 414 F.3d 187, 193 (1st Cir. 2005) (same).

- The Court held that Hofmann has no standing to pursue any claims against former defendant John Arcari. See Memorandum dated March 15, 2007 (Dkt. No. 209).

- All claims against former defendants Alan Ades and PwC were dismissed previously. See Order dated July 20, 2005 (Dkt. No. 83); Memorandum dated July 20, 2005, at 1 n.1 (Dkt. No. 84).[3]

II. SUMMARY JUDGMENT SHOULD BE GRANTED AS TO CHALLENGED STATEMENTS NOS. 10-39 BECAUSE THEY WERE MADE AFTER HOFMANN'S LAST PURCHASE OF ORGANOGENESIS STOCK.

Hofmann's final purchase of Organogenesis stock occurred on April 13, 2000. See Memorandum dated March 15, 2007, at 13 (Dkt. No. 209). As the Court held in its ruling on plaintiffs' Motion for Class Certification, as a matter of law Hofmann does not have standing to challenge any statements made *after* this purchase because he could not possibly have relied on or been misled by those statements, nor could they have inflated his purchase price. See id. at 12-13 (Hofmann "cannot show that he was harmed by the actions of Arcari individually as he purchased his last share before Arcari joined the company"); id. at 15 ("it would be undisputed that Arcari could not be liable on [Hofmann's] individual claim as Hofmann could not have

[3] Former plaintiffs Conen and Bowie withdrew from the case as both named plaintiffs and Lead Plaintiffs, and deemed themselves "absent class members." See Plaintiffs' Motion for Protective Order Disallowing the Deposition of Dr. Richard S. Conen and John H. Bowie, Jr. (Dkt. No. 154) (stating that Conen and Bowie withdrew as "Lead Plaintiffs and proposed class representatives in this action; referring to Bowie and Conen as mere "absent class members"; averring that "the Court's recent Orders granting their motions to withdraw confirm that neither [Bowie nor Conen] have any authority to speak on behalf of the Class, nor do they have any role in directing the course of this litigation"). By withdrawing as named plaintiffs and deeming themselves absent class members, Conen and Bowie withdrew any individual claims they might have once had. See Plaintiffs' Unopposed Motions for Withdrawal of Richard S. Conen and John H. Bowie, Jr. as Lead Plaintiff and Proposed Class Representative (Dkt. Nos. 131 and 151, respectively).

relied on Arcari's subsequent misrepresentations"; "Hofmann . . . does not have standing to proceed against Arcari").[4]

Challenged Statements Nos. 10-39 were made after April 13, 2000. Hofmann therefore does not have standing to challenge them, and summary judgment should be granted on all claims based on these statements.

III. SUMMARY JUDGMENT SHOULD BE GRANTED ON CHALLENGED STATEMENTS NOS. 1-9 BECAUSE THERE IS NO EVIDENCE THEY WERE FALSE OR MISLEADING.

Summary judgment also should be granted on Hofmann's claims based on Challenged Statements Nos. 1-9. Under Section 10(b), Hofmann must prove that the defendants made a material misrepresentation or omission of a material fact, such that the statements were false or misleading. See Dura, 544 U.S. at 341-42. Based on the undisputed facts, he cannot sustain this burden.

A. Challenged Statement No. 1 Was Not Fraudulent.

Statement Source	*Challenged Statement*	*Attributed To Defendant(s)*
Statement 1 Press Release Nov. 15, 1999 (Compl. ¶ 68)	"Apligraf is a revolutionary technology developed to provide significant advantages in wound healing. Apligraf is FDA approved, well-received by physicians and can be a highly cost-effective therapy for many patients. The key remaining piece of the puzzle is gaining broad, standardized reimbursement. Achieving standardized reimbursement for Apligraf is a top priority at both Novartis and Organogenesis and is being addressed aggressively by both companies."	Stein

[4] See also Gross v. Summa Four, Inc., 93 F.3d 987, 993 (1st Cir. 1996) (plaintiff had no standing to sue for statements made after his last purchase); Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1222 (1st Cir. 1996), superceded by statute on other grounds (same); In re Bank of Boston Corp. Sec. Litig., 762 F. Supp. 1525 (D. Mass. 1991) ("[A] Section 10(b) plaintiff has standing to challenge only those alleged misrepresentations upon which he reasonably relied in purchasing or selling his stock. Stated differently, a plaintiff has standing to challenge only those events occurring *prior* to the date of his last purchase or sale; for it is impossible for a plaintiff to have been misled by events occurring afterward.") (emphasis in original); Adair v. Sorenson, 134 F.R.D. 13, 16 (D. Mass. 1991) ("Plaintiff cannot establish that he relied on events which occurred after he purchased his stock. Any injuries sustained by [plaintiff] necessarily resulted from events occurring prior to his last purchase"); Konstantinakos v. FDIC, 719 F. Supp. 35 (D. Mass. 1989) (plaintiff who purchased stock in 1987 did not have standing to sue defendants for alleged misrepresentations made in 1988).

Hofmann contends that Organogenesis' press release dated November 15, 1999 was "false and misleading when made" because:

- It allegedly failed to disclose certain "material adverse factors" affecting the Company. See Compl. ¶ 76(a). In general, these "material adverse factors" were that *(i)* Organogenesis could not achieve profitability through the sale of Apligraf under the terms of the License and Supply Agreement with Novartis and was losing money on every unit of Apligraf sold; *(ii)* the Company was experiencing manufacturing and marketing problems; *(iii)* the Company needed additional funding in order to remain in business; and *(iv)* there was high management turnover and in-fighting. See Compl. ¶ 60.[5]

- "Contrary to defendants' representations that Apligraf was **'well-received by physicians'** and that achieving standardized reimbursement for Apligraf was being aggressively addressed by the Company, manufacturing and distribution problems, contamination issues, inadequate marketing support, and difficulties in obtaining reimbursement for Apligraf were causing increasing frustration among physicians, who were becoming less willing to re-order Apligraf for their patients. Continuing difficulties in obtaining reimbursement for Apligraf were not being adequately addressed by either Organogenesis or Novartis, which adversely affected Apligraf's future sales prospects." Compl. ¶ 76(c) (emphasis in original).

As set forth below, the November 15, 1999 press release was not misleading or material, the Company had no duty to disclose "material adverse factors" affecting its business, and at any rate the Company either disclosed those factors or they were obvious to reasonable investors.

1. There is no evidence of a material misstatement.

Hofmann challenges the statement that Apligraf was "well-received by physicians," Compl. ¶ 76(c), but the undisputed evidence – *i.e.*, the financial results that are set forth in SEC filings and that Hofmann never has challenged as inaccurate – makes clear that Apligraf, in fact, *was* well-received by physicians. Revenues from product sales increased from $42,000 in 1996 to $1,189,000 in 1998, *an increase of 2,731%*. See Defendants' Local Rule 56.1 Statement of Undisputed Material Facts ("SMF") ¶ 17. Revenues further increased to $1,844,000 in 1999,

[5] Hofmann contends that Challenged Statement Nos. 1-9 are false because they failed to disclose these "material adverse factors." See Compl. ¶¶ 76(a), 87(a). These allegations fail for the reasons set forth in Section III.A.2.

and continued to increase to $8,191,000 between 1999 and 2001, an increase of an additional 344%. See id. It also is undisputed that Apligraf unit sales increased during every quarter from Q3 1998 through Q1 2002. See SMF ¶¶ 14-16. All told, unit sales of Apligraf *increased* from 548 units in Q3 1998 to 7,102 units in Q1 2002. See id. "Obviously, there can be no securities fraud liability for a true statement." In re Loewen Group Inc. Sec. Litig., No. Civ. A. 98-6740, 2003 WL 22436233, at *13 (E.D. Pa. July 16, 2003).[6]

Hofmann also challenges the Company's statement that "[a]chieving standardized reimbursement for Apligraf is a top priority at both Novartis and Organogenesis and is being addressed aggressively by both companies." Compl. ¶¶ 68, 76(c). Hofmann, however, has not adduced any evidence that Organogenesis and Novartis were not aggressively pursuing standardized reimbursement for Apligraf. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986) (summary judgment appropriate where, as here, plaintiff bears the burden to prove essential element and lacks evidence to do so). Even if there was such evidence, the mere announcement that achieving standardized reimbursement is a "top priority" and is being "addressed aggressively" constitutes immaterial puffery because it did not alter the total mix of information and could not have been important to a reasonable investor's decision to buy or sell Organogenesis stock. See Fitzer v. Security Dynamics Techs., 119 F. Supp. 2d 12, 23 (D. Mass. 2000) ("the corporate puffery rule applies to loose optimism about both a company's current

[6] In any event, the statement that Apligraf was "well-received by physicians" also is immaterial as a matter of law because it constitutes a "loosely optimistic statement[] that [is] so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find [it] important to the total mix of information available." Shaw, 82 F.3d at 1219 (mere puffing to say that "the company's transition to selling its Alpha chip products was 'going reasonably well'"). Information is material "only if its disclosure would alter the 'total mix' of facts available to the investor and 'if there is a *substantial* likelihood that a reasonable shareholder would consider it important' to the investment decision." Milton v. Van Dorn Co., 961 F.2d 965, 969 (1st Cir. 1992) (quoting Basic, Inc. v. Levinson, 485 U.S. 224, 247 (1988)) (emphasis in original). For this reason, courts have found similar statements to be inactionable. See In re Splash Tech. Holdings, Inc. Sec. Litig., 160 F. Supp. 2d 1059, 1076-77 (N.D. Cal. 2001) ("strong" demand for products mere puffery); In re Southland Securities Corp. v. Inspire Ins. Solutions, 365 F.3d 353, 377 (5th Cir. 2004) (statement that "[t]he first quarter of 1998 was extremely significant for [defendant company]" is mere puffery).

state of affairs and its future prospects"); In re Galileo Corp. S'holders Litig., 127 F. Supp. 2d 251, 267 (D. Mass. 2001) (statement of "substantial revenue goals" that company "hoped to achieve" inactionable as a matter of law).

2. Defendants cannot be liable for failing to disclose the alleged "material adverse factors."

Because the allegedly false statements were neither misleading nor material, defendants had no duty to disclose any additional information regarding Organogenesis' financial or operational condition. A duty to disclose only arises where the alleged missing information is "needed so that what was revealed would not be so incomplete as to mislead." Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990) (en banc). There is no duty to disclose any more than what is necessary to make what was said true and not misleading. See, e.g., Cooperman v. Individual Inc., 171 F.3d 43, 51 (lst Cir. 1999) ("Disclosure of the business strategy supported by a majority of the directors did not obligate defendants also to disclose information about the extent to which each individual Board member supported that model").

None of the "materially adverse factors" that Hofmann contends were concealed – *i.e.*, the Company's ability to "achieve profitability" under the terms of the License and Supply Agreement with Novartis, Novartis' alleged "inexperienced and inadequately trained sales force," the state of Organogenesis' liquidity, and alleged management turnover and in-fighting (see Compl. ¶¶ 60, 76(a)) – undermine the veracity of what actually was said in Challenged Statement No. 1. Accordingly, there was no duty to disclose them. See Gross, 93 F.3d at 994-95 (statement that company received "significant orders" not misleading for failure to disclose that it was experiencing delays in closing contracts on such orders); Glassman v. Computervision Corp., 90 F.3d 617, 632-33 (1st Cir. 1996) (where company stated that backlog was usually low, it had not duty to disclose specific numbers).

Moreover, as set forth below, each of the "material adverse factors" either were disclosed or were obvious to any reasonable investor.

First, Hofmann cannot maintain any claim on the theory that the Company concealed its inability to achieve profitability under the License and Supply Agreement with Novartis, because the Company *disclosed* this Agreement in a SEC filing in March 1996. See SMF ¶ 7. Investors thus could evaluate the terms of the Agreement for themselves. Where a company discloses the material facts about a contract, investors obviously cannot state a fraud claim based on non-disclosure of those facts. See, e.g., Baron v. Smith, 380 F.3d 49, 57 (1st Cir. 2004) (affirming dismissal to challenge of disclosure of joint venture because the company disclosed the material facts in its Form 10-K); In re Segue Software, Inc. Sec. Litig., 106 F. Supp. 2d 161, 168 (D. Mass. 2000) (no liability where "relevant Form 10-K made no secret of the fact that the company selectively permitted returns").[7]

Additionally, it was *obvious* that Organogenesis was losing money on each sale of Apligraf based on the Company's SEC filings – *each* of which disclosed increasing Apligraf unit sales and revenues from year to year, see SMF ¶¶ 14-17, but at the same time disclosed increasing net losses from year to year. See SMF ¶¶ 11-13. Because Apligraf was the Company's only product, see Compl. ¶ 2, it *must* have been solely responsible for the

[7] Courts in other jurisdictions also have rejected similar claims that defendants concealed adverse financial information where, as here, there were extensive public disclosures regarding the company's financial condition. See, e.g., Hillson Partners Ltd. P'ship v. Adage, Inc., 42 F.3d 204, 212 (4th Cir. 1994) (securities laws do not require disclosure of information that is already in the public domain); In re World of Wonder Sec. Litig., 35 F.3d 1407, 1415-16 (9th Cir. 1994) (statements that company "expected to have sufficient cash to operate through March 31, 1998" not misleading in light of disclosure regarding risks); The Winer Family Trust v. Queen, No. Civ.A. 03-4318, 2004 WL 2203709, at *20 (E.D. Pa. Sept. 27, 2004) (dismissing claims based on alleged omission regarding liquidity where, as here, company disclosed liquidity issues); Berger v. Beletic, 248 F. Supp. 2d 597, 604 (N.D. Tex. 2003) ("no legal obligation to disclose that [the company] might be subject to a going concern modification . . . . Several public filings before and during the Class Period indicated [the company] was operating at a loss, and it was in need of additional capital that it may not be able to secure. Companies do not have a duty to disclose obvious possibilities.").

Company's losses. Organogenesis also told investors that "production costs" exceeded "product sales" for Apligraf. See SMF ¶ 22.

Organogenesis was not obligated to say any more. "The federal securities laws were intended to protect the average, reasonable investor, not the most unworldly naïf. They do not require a company to state the obvious." In re Numerex Corp. Sec. Litig., 913 F. Supp. 391, 400 (E.D. Pa. 1996); see also Vosgerichian v. Commodore Int'l, 862 F. Supp. 1371, 1377 (E.D. Pa. 1994) (alleged omission of drop in sales price not actionable as it was implicit based on drop in earnings and sales; "when the undisclosed elements of a company's financial situation are obvious from that which the company *does* disclose, the company cannot be held liable for a material omission") (emphasis in original).[8]

Second, Hofmann's claim that Organogenesis should have disclosed Novartis' alleged "inexperienced and inadequately trained sales force" is without merit. No reasonable investor possibly could have thought that Novartis (or anyone) had experience selling a "living-tissue product" because the market was told that "Apligraf is the only mass-manufactured product containing living human cells." SMF. ¶ 2. The "fact that a new product might face problems in the market is obvious to a reasonable investor, and therefore omission of it is not culpable." In re Boston Tech. Inc. Sec. Litig., 8 F. Supp. 2d 43, 63 (D. Mass. 1998).

Organogenesis also explicitly disclosed the obvious risk that Novartis might fail in its Form 10-K for 1998: "[o]ur collaborators might not be successful in gaining market acceptance for our products." SMF ¶ 25. Moreover, "poor management is a risk that every investor takes." Fitzer, 119 F. Supp. 2d at 31. Nor is there any evidence to suggest that Novartis failed to market

[8] See also In re Donald J. Trump Casino Sec. Litig., 7 F.3d 357, 377 (3d Cir. 1993) (no need to disclose the "obvious implications of the already weakened economic conditions in the Northeast" because "[t]he federal securities laws…do not compel [a company] to state the obvious"); In re Mobile Tele. Techs. Corp. Sec. Litig., 915 F. Supp. 828, 838 (S.D. Miss. 1995) ("no duty to disclose the obvious fact that competition would increase" when new competitor entered market).

Apligraf effectively. As noted earlier, Apligraf sales increased every quarter from Q3 1998 to Q1 2002. See SMF ¶¶ 14-16.

Third, summary judgment is warranted on Hofmann's claim that defendants concealed Organogenesis' liquidity because all material facts were disclosed to investors. For example, in its Form 10-K for 1998, Organogenesis disclosed that it had incurred net losses for every year since 1994, including a $14 million net loss for 1998, and further disclosed that "[w]e may incur additional losses as expenditures continue to increase due to expansion of operations and research programs." SMF ¶ 10. In its Form 10-K for 1999, Organogenesis similarly disclosed that it consistently lost money during its entire 15-year history:

> Organogenesis Inc. was founded in 1985. *We have incurred operating losses in every year of our existence.*

Id. All told, Organogenesis announced aggregate net losses of *$41.3 million* during fiscal years 1996-1998 and aggregate net losses of *$87 million* during fiscal years 1999-2001, for a total net loss of $128.3 million for the five-year period from 1996 to 2001. See SMF ¶ 12. Moreover, the company's losses increased every year from 1998 to 2001: $14 million loss in 1998; $28.3 million loss in 1999; $28.6 million loss in 2000; and $30.1 million loss in 2001. See SMF ¶ 13.

The Company also expressly warned investors that it expected its losses to continue and might never become profitable:

> OUR COMPANY HAS A HISTORY OF LOSSES AND WE EXPECT TO CONTINUE TO INCUR LOSSES
>
> We have not achieved profitability and *expect to continue to incur net losses*. The extent of future losses and the time required to achieve profitability is *highly uncertain*.

SMF ¶ 19 (Form 10-K for 1999). Hofmann could not have been misled, as he contends, that Organogenesis would "achieve profitability in the foreseeable near-term." Compl. ¶ 5.

And, to the extent it was not obvious, Organogenesis further warned investors that, because it always lost money and might never be profitable, it would have to curtail or even cease operations if it could not raise additional funds:

> Additional funds may not be available when required on acceptable terms. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs . . . resulting in potential material adverse effect on our financial condition and results of operations.

SMF ¶ 21 (Form 10-K for 1998).

Given these disclosures, no reasonable investor could have possibly believed anything other than that Organogenesis had always lost money, likely would continue to lose money in the near future, and faced liquidity and financing issues. See Baron, 380 F.3d at 55 ("Plaintiffs' claim fails because [defendant] disclosed the material facts that would lead a reasonable investor to make an informed decision regarding the purchase of stock"); In re Segue Software, 106 F. Supp. 2d at 168 (no liability where "relevant Form 10-K made no secret of the fact that the company selectively permitted returns").

Fourth, Hofmann cannot maintain a claim for the alleged non-disclosure of "management turnover" and "in-fighting." See Compl. ¶¶ 60, 76(a). "[A] claim of fraud cannot arise from poor management," Fitzer, 119 F. Supp. 2d at 33 (citing Santa Fe Indus., Inc. v. Green, 430 U.S. 462, 479 (1977)), or high management turnover. Hofmann cannot dispute that Organogenesis disclosed changes in senior management in its public filings and press releases. See Compl. ¶¶ 122, 147. Having so disclosed, Organogenesis had no obligation to state the obvious that management turnover can be disruptive. See In re Craftmatic Sec. Litig., 890 F.2d 628, 640 (3d Cir. 1990) (no liability under securities laws for "failure to disclose" managerial "incompetence"); Berger, 248 F. Supp. 2d at 597 (no duty to disclose "obvious possibilities").

B. Challenged Statement No. 2 Was Not Fraudulent.

Statement Source	*Challenged Statement*	*Attributed To Defendant(s)*
Statement 2 10-Q for Q3 1999 Nov. 15, 1999 (Compl. ¶ 70)	"We expect Apligraf commercial sales to increase." "Production costs exceeded product sales due to the start-up costs of new product introduction and the high costs associated with low volume production. We expect production volume to increase and our margins to improve. We expect to continue to expand manufacturing operations and advance the product pipeline during the remainder of 1999 and into 2000."	Stein Lopolito

Hofmann contends that Organogenesis' Form 10-Q for Q3 1999 (dated November 15, 1999) was "false and misleading when made" because:

- The representation that the Company expected "Apligraf commercial sales to increase" was untrue "given the marketing problems that Novartis was experiencing because of inadequate marketing support and the problems with the manufacturing and distribution of Apligraf that were causing frustration among purchasers, leading to reluctance among physicians to order or re-order Apligraf." Compl. ¶ 76(e).

- The Company's representations that production volume would increase and that as a consequence of that increase the Company's margins would improve was misleading because (i) the Company was experiencing problems in manufacturing Apligraf and there was "no way" the Company could feasibly mass-produce Apligraf, and (ii) the Company was losing money on every sale of Apligraf because of the disadvantageous terms of the License and Marketing Agreement with Novartis. Compl. ¶ 76(b).

These allegations fail as a matter of law for a variety of reasons.

First, contrary to Hofmann's allegation (Compl. ¶ 76(e)), there was nothing fraudulent about the Company's statement that it expected "Apligraf commercial sales to increase." In fact, sales of Apligraf increased *every quarter* from Q3 1998 through Q1 2002. See SMF ¶¶ 14-16. Defendants cannot be liable for a prediction that came true. See In re Loewen Group, 2003 WL 22436233, at *13. Nor does Hofmann have any evidence that any defendant did not believe that the correct prediction was not attainable. See In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1432-33 (3d Cir. 1997) (companies protected from liability when disclosing internal

forecasts except to the extent such forecasts were unreasonable when made); In re Advanta Corp. Sec. Litig., 180 F.3d 525, 535-36 (3d Cir. 1999) (opinions, predictions and other forward-looking statements are not actionable unless the speaker does not genuinely and reasonably believe them when they are made).

Second, the Company's statement that it "expect[ed] production volume to increase" was not misleading. By Hofmann's own admission, Apligraf was being produced in 2001 at a rate of more than 40,000 units per year. See Compl. ¶ 136. The Company also warned investors of the risk of manufacturing problems due to the complexity of the manufacturing process in its Form 10-K for 1998. See SMF ¶ 23 (because Apligraf manufacturing process is "complex," there may be difficulty manufacturing enough "to satisfy the demands . . . and our results of operations will be hurt"). Moreover, the market did not need to be told that problems sometimes arise when manufacturing a "revolutionary" medical therapy, Compl. ¶ 49, since this was obvious. See supra § III.A. (citing cases).

Third, as set forth above, Hoffmann cannot maintain a claim that the Company concealed the fact that it lost money on each sale of Apligraf. See Compl. ¶ 76(b). The Company disclosed losses in every year of its existence and warned investors that it "expect[ed] to continue to incur net losses." See supra § III.A. Furthermore, the Company disclosed the License and Supply Agreement, which contained terms governing the split of revenue between Organogenesis and Novartis, thus enabling investors to evaluate losses on sales of Apligraf. See SMF ¶ 7. Accordingly, it was obvious that the Company lost money on each sale of Apligraf.

Fourth, summary judgment is warranted on Hofmann's challenge to the Company's statement that it "expect[ed] . . . margins to improve" because the Company's public filings demonstrate that this prediction came true. Indeed, the Company's gross profit margins did

improve, albeit modestly, between the first and second quarters of 2000. See SMF ¶ 18. In any event, this statement, which is a projection, is protected by the safe harbor of the Private Securities Litigation Reform Act of 1995 ("PSLRA") and thus inactionable.

C. Challenged Statement No. 3 Was Not Fraudulent.

Statement Source	***Challenged Statement***	***Attributed To Defendant(s)***
Statement 3 Press Release Dec. 2, 1999 (Compl. ¶ 69)	"Organogenesis Inc. [] today announced that in November a record number of Apligraf® US commercial units were sold and a record number of US medical centers ordered Apligraf for the first time." "'The growth now being seen is due to new Apligraf marketing and sales initiatives by Novartis and is independent of the efforts underway to gain standardized reimbursement for the product,' said Alan Tuck, Chief Strategic Officer."	Tuck

Hofmann contends that Organogenesis' press release dated December 2, 1999 was "false and misleading when made" because:

> "The Company's 'statements touting the 'record number' of sales in November 1999 and Novartis' 'new Apligraf marketing and sales initiatives' were materially misleading and incomplete given that, as confirmed by several former employees of Organogenesis, the Company was experiencing serious manufacturing and marketing problems that were inhibiting sales and damaging future sales development prospects. Further, as defendants knew but did not disclose, Novartis' marketing team did not have the proper training experience or expertise in selling a product like Apligraf, with the result that Novartis' efforts to market Apligraf suffered significantly." Compl. ¶ 76(b).

Summary judgment should be granted on this claim because Organogenesis' statement that "a record number of Apligraf commercial units were sold" in November 1999 was *true*. Hofmann does not contend otherwise in the Complaint, and certainly cannot adduce evidence to the contrary. Nor does he contend that Novartis did not, in fact, implement "new Apligraf marketing and sales initiatives."

Unable to dispute the truth of these statements, Hofmann attempts to establish liability based on his generic non-disclosure theories – in particular, that the Company failed to disclose

that it "was experiencing serious manufacturing and marketing problems that were inhibiting sales and damaging future sales development prospects" and that "Novartis' marketing team did not have the proper training experience in selling a product like Apligraf." Compl. ¶ 76(b). However, there was no duty to disclose any of this information because it was not necessary to make what was said true and not misleading. See supra § III.A. The Company accurately reported "record" sales in November 1999. No liability can attach based on accurate reports of historical results. See, e.g., Suna v. Bailey Corp., 107 F.3d 64, 68 (1st Cir. 1997) ("defendants may not be held liable under the securities laws for accurate reports of past successes, even if present circumstances are less rosy") (quoting Serabian v. Amoskeag Bank Shares, Inc., 24 F. 3d 357, 361 (1st Cir. 1994)); Guerra v. Teradyne, Inc., 2004 WL 1467065 (D. Mass. Jan. 16, 2004) (same); Boston Tech., 8 F. Supp. 2d at 69 ("None of the financial reporting here… is alleged to have been false. Accurate accounts of past financial results without more are not actionable.").

Furthermore, as explained above, Hofmann cannot maintain a claim for the non-disclosure of Novartis' lack of experience selling a product like Apligraf because: *(i)* this was obvious to any reasonable investor; *(ii)* Organogenesis nevertheless disclosed this risk; and *(iii)* there is no evidence to suggest that Novartis did not effectively market Apligraf given the nearly 400% increase of Apligraf sales from Q3 1999 to Q1 2001. See supra § III.A. Hofmann similarly cannot maintain a claim on the theory that defendants should have disclosed "serious manufacturing problems": *(i)* Apligraf sales increased in every quarter from Q3 1999 to Q1 2001, and there is no proof that production did not increase to meet this demand; *(ii)* Apligraf was being produced at a rate of 40,000 units per year in 2001; and *(iii)* the Company expressly warned investors of the risk of manufacturing problems. See supra § III.B.

D. Challenged Statement No. 4 Was Not Fraudulent.

Statement Source	***Challenged Statement***	***Attributed To Defendant(s)***
Statement 4 Presentation at Hambrecht & Quist Annual Healthcare Conference Jan. 13, 2000 (Compl. ¶ 73)	Plaintiffs do not allege any particular statement, only that "Laughlin reiterated former guidance and further conditioned investors to believe that the Company was operating according to plan."	Laughlin

Hofmann's claim based on Laughlin's presentation at the Hambrecht & Quist Annual Healthcare Conference on January 13, 2000 fails because he has not even identified an *actual statement*. Reiterating "former guidance" and "condition[ing] investors to believe that the Company was operating according to plan," Compl. ¶ 73, are not actual statements; rather, they are Hofmann's (or his lawyers') characterizations of whatever unidentified statement Mr. Laughlin actually may have made. Summary judgment therefore should be granted on this claim. See In re Copley Pharm., Inc., Civ. A. No. 94-11897, 1995 WL 169215, at *2 n.5 (D. Mass. Mar. 16, 1995) (securities laws are about "actual statements").

E. Challenged Statement No. 5 Was Not Fraudulent.

Statement Source	***Challenged Statement***	***Attributed To Defendant(s)***
Statement 5 Interview with Wall Street Transcript Jan. 14, 2000 (Compl. ¶ 73)	"We're in the process of changing medical practice, and that has gone slower than we'd like. But we're not concerned that we won't ultimately be successful."	Laughlin

Hofmann contends that Laughlin's interview dated January 14, 2000 was "false and misleading when made" because:

> "Contrary to defendants' representations that they were 'not concerned that we won't ultimately be successful,' defendants knew that the Company's ultimate prospects for achieving profitability were severely compromised by the fundamental problems alleged in paragraphs 59-67, *supra*, including the

> Company's serious manufacturing and marketing problems, its inability to access as necessary adequate funding to keep the Company viable, the difficulties in achieving reimbursement for Apligraf, and the disruptive effect on operations that high turnover and infighting among the Company's senior management was having and would continue to have for the foreseeable future." Compl. ¶ 76(f).

As a matter of law, defendants cannot be liable for Laughlin's statement "we're not concerned that we won't ultimately be successful" because it constitutes immaterial puffery. See, e.g., Shaw, 82 F.3d at 1219 ("confident that DEC was pursing the right strategy" immaterial); Colby v. Hologic, Inc., 817 F. Supp. 204, 211 (D. Mass. 1993) ("Prospects for long-term growth are bright" inactionable); In re Parametric Tech. Corp. Sec. Litig., 300 F. Supp. 2d 206, 217-18 (D. Mass. 2001) ("we continue to have confidence in the fundamental strength of our business and in our strong competitive position" inactionable); In re Galileo, 127 F. Supp. 2d at 267 (statement of "substantial revenue goals" that company "hoped to achieve" inactionable); San Leandro Emergency Med. Grp. v. Philip Morris Cos., 75 F.3d 801, 807, 811 (2d Cir. 1996) (statement that company "expect[ed] . . .another year of strong growth in earnings per share" inactionable). Hoffmann's non-disclosure theory, see Compl. ¶ 76(f), also fails for the reasons set forth above, *i.e.*, no duty to disclose. See supra §§ III.A., B.

F. Challenged Statement No. 6 Was Not Fraudulent.

Statement Source	***Challenged Statement***	***Attributed To Defendant(s)***
Statement 6 Amended 10-Q for Q3 1999 Feb. 14, 2000 (Compl. ¶¶ 74, 75)	"We expect Apligraf commercial sales to increase." "The accompanying unaudited consolidated financial statements of Organogenesis Inc., have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented. The results of operations for the nine months ended September 30, 1999 are not necessarily indicative of the results to be expected for the	Laughlin Lopolito

	year ending December 31, 1999." "Production costs exceeded product sales due to the start-up costs of new product introduction and the high costs associated with low volume production. We expect production volume to increase and our margins to improve. We expect to continue to expand manufacturing operations and advance the product pipeline during the remainder of 1999 and into 2000."	

Hoffmann contends that Organogenesis' Amended Form 10-Q for Q3 1999 dated February 14, 2000 was "false and misleading when made" because it allegedly "did not reflect the true financial condition of the Company." Compl. ¶ 76(g). This claim is without any basis. Every financial statement that Organogenesis filed with the SEC during the Class Period contained accurate financial information (including revenues, expenses, profits/losses, margins, and sales of Apligraf) and complied with Generally Accepted Accounting Principles ("GAAP"). See SMF ¶ 9. Hofmann does not even contend otherwise. Indeed, this Court dismissed PwC from the case – even under the generous Rule 12(b)(6) standard – because the Complaint did not identify any supposed error in the publicly-reported accounting. See Dkt. No. 84. Accordingly, the Company's Amended Form 10-Q for Q3 1999 accurately reflected the financial condition of the Company.

Additionally, Hoffman cannot base any claim on the Company's statement that "[w]e expect Apligraf commercial sales to increase" because sales of Apligraf, in fact, increased every quarter after February 14, 2000. See SMF ¶¶ 14-16 (Apligraf unit sales increased every quarter from Q3 1999 to Q1 2001 for a total increase of almost 400%). Similarly, any challenge to the Company's statement that it "expect[ed] . . . margins to improve" fails because the Company's

public filings demonstrate that this prediction came true. The Company's gross profit margins did improve, albeit modestly, between the first and second quarters of 2000. See SMF ¶ 18.[9]

Finally, any non-disclosure claim fails for the reasons set forth above. See supra §§ III.A., B.

G. Challenged Statement No. 7 Was Not Fraudulent.

Statement Source	***Challenged Statement***	***Attributed To Defendant(s)***
Statement 7 Press Release Feb. 24, 2000 (Compl. ¶ 77)	"We are pleased the strong interest in our Company resulted in an over-subscription to this offering."	Tuck

Hoffmann claims that the Company's press release dated February 24, 2000 was "false and misleading when made" on the purported ground that it "presumably placed Organogenesis in a position of having more money than needed to fulfill defendants' near-term objectives." Compl. ¶ 78. This is an untenable claim. The actual statement that the offering was "oversubscribed" was undisputedly true, and Hofmann does not – and cannot – contend otherwise. The "presumption" that the proceeds from the offering gave Organogenesis "more money than needed" has nothing to do with the actual statement. See generally In re Copley Pharm, 1995 WL 169215, at *2 n.5 (it is of no import whether a statement "furthered [an] impression" or "fostered [a] sense"; only actual statements are proper subjects of securities litigation).

Moreover, the Company's statement that it was "pleased in the strong interest in the Company," in addition to being indisputably true, is immaterial as a matter of law. See Greebel v. FTP Software, 194 F.3d 185, 189 (1st Cir. 1999) (being "pleased" inactionable puffery); In re

[9] In any event, this statement, which is a projection, is protected by the PSLRA safe harbor and thus inactionable.